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10/038,565	10/19/2001	Yuusuke Nonomura	871A 3068	7124

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EXAMINER

ROSE, SHEP K

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/23/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038565

Applicant(s)

NONMONUMENTAL

Examiner

SIDOR ROSE

Group Art Unit

1604

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 05/08/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☐ Claim(s) 1, 3, 5, 6, 7, 10, 12, 14, 16, 17 is/are pending in the application.
- Of the above claim(s) 2, 4, 8, 9, 11, 13, 15, 17 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3, 5, 6, 7 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 2, 4, 8, 9, 10, 12, 14, 15, 17 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Applicants have filed application Serial No. 10/038,565 on October 19, 2001 with 18 composition claims and two sheets of drawings, (Figures 1 and 2) and claim an October 20, 2000 Japanese priority date.

The January 3, 2003 and May 8, 2003 responses to the July 5 2002 and March 4 2003 office actions have been considered and the attorney's declaration and translation of the Japanese priority documents are acceptable per MPEP 608.01 (P) (a) for the purposes filed.

Claims 11, 13, 15, and 18 are cancelled.

As noted on page 3 of the March 4 2003 office action, claims 2, 4, 8 to 10, 12, 14, 16, and 17 are withdrawn, Rule 142 (B) as constructively non-elected subject matter, the first example, to compositions (which can obviously be swished in the mouth (typically) then swallowed orally comprising azithromycin and amphotericin B antifungal antibiotics are constructively elected as the most comprehensive species and claims 1, 3, 5 to 7 generic thereto (or readable thereon).

The Specification has been objected to as it fails to include, any page one (it starts on page 2), or any separate paragraph entitled "Brief Description of the Drawings". Where is it? According to the recitals of the bottom 5 lines of page 12 of the Specification, Figure 1 is the chemical structure of amphotericin B antifungal agent, while Figure 2 is the chemical structure of azithromycin antibiotic.

Figures 1 and 2 were objected to for failing to contain these captions, but new drawings are required (since the USPTO Draftsman no longer corrects or amends drawings).

The eighteen original composition claims recited plural active agent species and were held to be improperly indefinite and alternative in each recitation of “or” and “such as”, which appeared in line 1 of claims 1, 2, and 3.

The most comprehensive active agent species composition claims (claims 1, 3, 5 to 7) are to the combination of amphotericin B antifungal agent (claim 5) with azithromycin antibiotic (claim 7), which are constructively elected by original presentation, for oral dental or periodontal treatment.

Page 4 of the specification indicates that a “first example” is a medication consisting of amphotericin B (“Halizon”) of Fig. 1 and azithromycin (“Zithromax”) in Fig 2 as its components, for treating periodontitis.

Pages 5 and 6 (top 6 lines) indicate “variations of the “first example” to include denture disinfections of Candida growth.

Pages 6 to 9 indicate (non-elected) plural combined anti-bacterial antifungal agent species: A1, A2, B1, B2, C1, C2, D1, D2, E1, E2, F1, F2 and G as 2, 3, and 4 product mixes, mentioning the addition of other antifungal agent species: metronidazole (Flagyl), fluconazole (Diflucan) and miconazole, in addition to amphotericin B, to anti-bacterial antibiotics, including tetracycline, penicillin, “Kefral” cephem-type, “ciproxan” ciprofloxacin, in addition to azithromycin (“Zithromax”) antibiotic, all of which combinations are encompassed by the broad terms of claim 1 “an antifungal agent and an antibiotic”.

Pages 9 and 10 relate to a “Second Example” (non-elected) which adds plural species of known agents to be used with the medicines of the first example, while pages

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10 and 11 list plural species of carriers, page 12 lists more possible uses, and page 12 possible new antibiotic synthesis, while claims 2 to 4, 8 to 18 recite one or more of these further plural active agent and plural carrier species.

As noted above, while applicants' first example consists of amphotericin B (antifungal agent) and azithromycin (antibiotic) there is no claim presented corresponding thereto. None of the elected composition claims recite consisting of, claims 5 and 7, and claims 1 and 6, generic thereto, call for a composition comprising (A) amphotericin B, or another antifungal agent, and (B) azithromycin, or another antibiotic, or another macrolide antibiotic, in any proportions of (A) to (B), to treat species of bacteria and species of fungi sensitive to (A) and to (B) not only in the periodontal pockets, but also as encountered in dental oral care, in the region of dental carries lesions, in dental pulp, in the presence of persistent pus discharge and biofilm, root canal, bone infection and also to treat candida growth in denture wearers with tooth and dental root caries and periodontitis.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5, 6, 7 stand and/or are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of:

Brizzolari et al (I) (claims 2 and 22, column 2, lines 36 to 59, column 8, lines 45 to 53) periodontal mixture of encompassed species of antibiotics and antifungal agents;

Brizzolara et al (II) (claim 8, column 2, lines 13-34) periodontal mixture of encompassed species of antibiotics and antifungal agents;

Dunn (column 9, lines 11 to 20) periodontal treatment with encompassed species of antifungal agents, like mystation metronidazole, and plural encompassed species of antibacterial antibiotics.

Rajaiah et al (I-II) (claim 17) denture adhesives with mixtures of encompassed species of antibiotics and antifungal agents;

Little et al, identifying and treating oral individual and mixed flora candida and other fungus species infections and bacterial infections with individual and mixtures of amphotericin B, and other anti-fungal agents: mystatin, azoles, griseofulvin (column 11, lines 1 to 67) and anti-bacterial antibiotics including azithromycin (column 12, lines 31, 38, to column 15, line 51) after first identifying the pathogenic species of fungi and of bacteria (See the entire document);

Brockbank et al, (not an oral treatment agent) as antibiotic “cocktail” of antifungal agents: amphotericin B and fluconazole, and encompassed plural species of

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antibacterial antibiotic, to substantially inhibit both fungal (especially candida) and bacterial growth, (see especially, columns 1 to 3, 24 to 28 and claim 1;)

Ayon-Covarrubias, including encompassed species of antibiotics, like gentamycin, into dental use antifungal treatment of Candida composition, with encompassed species of antifungal agents, (see claims 2, 3, 9, and column 2, lines 11 to 13, 62, and column 3, lines 8.

The statement of intended use in the preamble of composition claims 1, 5, 6 does not render it patentable, In re Sinex 135 USPQ 302, 305; In re Zierden, 162 USPQ 102, 104, In re Person, 181 USPQ 144.

Claims 1, 3, 5, 6, 7 stand/and/or are rejected under 35 U.S.C. 103(a) as being unpatentable over Little et al (details as noted above) in view of which the specific combination consisting of (A) amphotericin B antifungal agent and (B) Azithromycin antibacterial antibiotic would be immediately envisioned, once tests established the presence of both pathogenesis fungi species as well as pathogenic bacteria species susceptible to (A) and to (B). In re Kerkhoven, 205 USPQ 1069, 1072, and (as noted above) no weight is given to the statement of intended use in the preamble of these composition claims.

From the teaching of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in cursive script, appearing to read "Shep Rose".

Rose/tgd
July 21, 2003

**SHEP K. ROSE
PRIMARY EXAMINER**